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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,345

01/31/2006

Daniel R. Greve

428-US-PCT

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01/23/2009

LUNDBECK RESEARCH USA, INC.

ATTENTION: STEPHEN G. KALINCHAK, LEGAL

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PARAMUS, NJ 07652

EXAMINER

YOUNG, SHAWQUA

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

01/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/549,345	Applicant(s) GREVE ET AL.	
	Examiner SHAWQUIA YOUNG	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 18-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/28/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-31 are currently pending in the instant application.

I. *Priority*

The instant application is a 371 of PCT/DK04/00162, filed on March 12, 2004 which claims benefit of US Provisional Application 60/454,580, filed on March 14, 2003 and Foreign Application DENMARK PA200300392, filed on March 14, 2003.

II. *Information Disclosure Statement*

The information disclosure statement (IDS) submitted on March 28, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

III. *Restriction/Election*

A. Election: Applicant's Response

Applicants' election with traverse of Group I in the reply filed on September 26, 2008 is acknowledged. The traversal is on the ground(s) that: (1) that the claims have unity of invention.

All of the Applicants' arguments have been considered but have not been found persuasive. It is pointed out that the restriction requirement is made under 35 U.S.C. 121. 35 U.S.C. 121 gives the Commissioner (Director) the authority to restrict applications to several claimed inventions when those inventions are found to be independent and distinct. The Examiner has indicated that more than one independent

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and distinct invention is claimed in this application and has restricted the claimed subject matter accordingly.

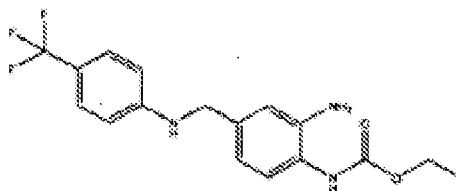
However, the Examiner wants to point out that the special technical feature is considered the core structure of formula I but does not include the variables because the variables are not constant. The special technical feature in the claims does not provide a contribution over the art and therefore lacks unity. The reference Litvinenko supports that Applicants' special technical feature does not provide a contribution over the art. The Examiner wants to emphasize that the special technical feature in Applicants' claims is the core structure in formula I and the variables are not included.

The Restriction Requirement detailed the reasons for restriction between the groups. Different search considerations are involved (i.e., class/subclass searches, databases searches, etc.) for each of the groups listed. The inventions are classified into classes 514, 544, 546 and 548. However, each Class 514, 544, 546 and 548 encompasses numerous patents and published applications. For instance, Class 514 contained 165,171 patents and published applications. Therefore it would constitute a burden on the Examiner and the Patent Office's resources to examine the instant application in its entirety. The restriction requirement is deemed proper and made final.

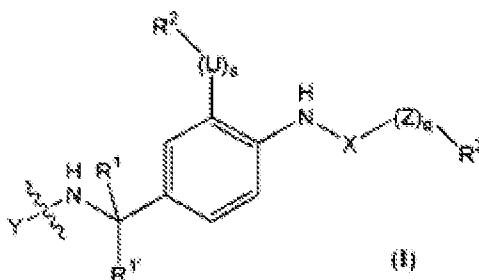
Subject matter not encompassed by elected Group I are withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected inventions.

B. Status of the Claims

i. Scope of the Search and Examination of Elected Subject Matter



The above structure is the provisional elected species. Thus the scope of the search and examination of the elected subject matter is the compounds of formula (I) in claims 1-17 wherein:



U is $\text{NR}^{2'}$;

s is 1;

R² is hydrogen;

R^{2'} is hydrogen;

X is CO;

Z is O;

q is 1;

R¹ and **R^{1'}** is as defined in claim 1;

R³ is as defined in claim 1;

Y is the group of formula IX;

f is as defined in claim 1; and

R⁵ is as defined in claim 1 excluding two R⁵ substituents together form a 5-8 membered ring which optionally contains one or two heteroatoms.

ii. Extended Prior Art Search M.P.E.P. §803.02

If upon examination of the elected species, no prior art is found that would anticipate or render obvious the instant invention based on the elected species, the search of the Markush-type claim will be extended. See M.P.E.P. § 803.02 (2001). If prior art is then found that anticipates or renders obvious the non-elected species, the Markush-type claim will be rejected. It should be noted that the prior art search will not be extended unnecessarily to cover all non-elected species. Should Applicant overcome the rejection by amending the claim, the amended claim will be reexamined. Id. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. Id. In the event prior art is found during reexamination that renders obvious or anticipates the amended Markush-type claim, the claim will be rejected and the action made final. Id.

As indicated above, Examiner searched the compound based on the elected species, above, in response to the requirement to restrict the products of Formula (I), wherein: there was no prior art of record that

anticipated or rendered obvious the elected species and therefore the scope of the subject matter was **extended or broadened** in pursuant to M.P.E.P. § 803.02.

The prior art search was extended to include the products of formula (I) wherein:

U is as defined in claim 1;

s is 0 or 1;

R² is as defined in claim 1 and

R^{2'} is as defined in claim 1.

iii. Non-elected Subject Matter Withdrawn 37 C.F.R. §1.142(b)

The non-elected subject matter withdrawn are the compounds of formula (I) in claims 1-17 (in part) which are not disclosed in sections (i) and (ii).

IV. Objections

Claim Objection-Non Elected Subject Matter

Claims 1-17 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should submit an amendment deleting the non-elected subject matter.

Specification

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, *e.g.*, "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

Complete revision of the content of the abstract is required on a separate sheet.

V. Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Shawquia Young/

Examiner, Art Unit 1626

/Rebecca L Anderson/

Primary Examiner, Art Unit 1626